

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

FEDERAL TRADE COMMISSION, Plaintiff, v. DIRECT MARKETING CONCEPTS, INC, et al, Defendants	CIVIL ACTION NO. 04-CV 11136GAO
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DECLARATION OF JANE TEAS, PH.D.

I, Jane Teas, hereby declare as follows:

Introduction and Qualifications

1. I am a researcher at South Carolina Cancer Center, at the Arnold School of Public Health, at the University of South Carolina. I have been employed as a Research Assistant Professor since 1999. My training in Pathobiology at Johns Hopkins University, and postdoctoral training at Harvard School of Public Health have been interdisciplinary, integrating issues of public health and seaweed.
2. I have conducted several studies of the health benefits of seaweed, and written original articles published in peer-reviewed journals and books concerning seaweed.
3. I am a member of the American Association of Cancer Research, the International AIDS Society, and the International Seaweed Association.
4. I have served as a reviewer for Journal of Nutrition and the International Immunopharmacology

5. A true and accurate copy of my curriculum vitae appears as Attachment 1 to this Declaration.

Review of Sea Vegg by FarmaSea Product Information

6. I have been provided with a Certificate of Analysis for Sea Vegg, showing that it contains no toxic heavy metals or microbial contaminants.
7. I have also been provided with the Sea Vegg infomercial. Based on the information in the transcript, Sea Vegg contains a variable combination of 12 seaweeds harvested according to seasonal availability along the Irish coast.
8. No specific information about which seaweeds have been used was provided. In theory they would include the common commercially harvested seaweeds in Ireland, which would encompass red seaweeds (*Chondrus crispus*, *Palmaria palmate*, *Phorphyra*, *Himanthalia elongate*), green seaweeds (*Ulva lactuca*, *Enteromorpha sp.*), and brown seaweeds (*Laminaria digitata*, *Laminaria hyperboreana*, *Laminaria saccharina*, *Alaria esculenta*).
9. Instructions on dose range from 1-3 capsules/day.

Summary of Findings

10. I have been asked me to review the scientific literature that would support the claims made for the health benefits of Sea Vegetation. In particular, whether SeaVegetation could treat or prevent cancer, fibromyalgia, diabetes, arthritis, or multiple sclerosis, or cause weight normalization.

11. Based on my review of the literature and my own laboratory and clinical findings, evidence exists for the health claims of fibromyalgia, diabetes, and arthritis. Evidence of cancer prevention or treatment potential are logical based on traditional medical systems and some scientific studies, but probably are premature at this time. However, since seaweeds are consumed in many countries where cancer rates are generally lower than in the US, the addition of seaweeds to the average American diet may help promote health.

Acute benefits

12. In reading the transcript, it is unclear what immediate benefits are being promised but seems that weight control and an increase in energy levels may be implied. In my experience of giving 5 grams/day (10 x 500 mg capsules/day) of *Alaria esculenta* to 32 healthy postmenopausal women in Massachusetts, and following them for 7 weeks, none of the women reported weight changes. But, they did have positive results.

13. Of our initial 34 subjects, two women dropped out of our study because of adverse reactions to seaweed; one woman developed red itchy eyes and a skin rash, and one woman experienced gastric reflux (heartburn). Both of these women had had similar symptoms before, and both had their symptoms disappear when they stopped taking the seaweed.

Below is a table of the kinds of side effects, both positive and negative, that the other women experienced:

Side effects (32 women after 7 weeks on seaweed)

	Better	Worse
Hot flashes	1	3
Sleep	2	2
Skin	2	1
Constipation	3	0
Energy	7	1
Nails	9	1
Hair	11	0
Gassy/bloat	0	5
Indigestion	0	2
Bowel movement urgency	0	1
No changes	6	13
No data	1	1

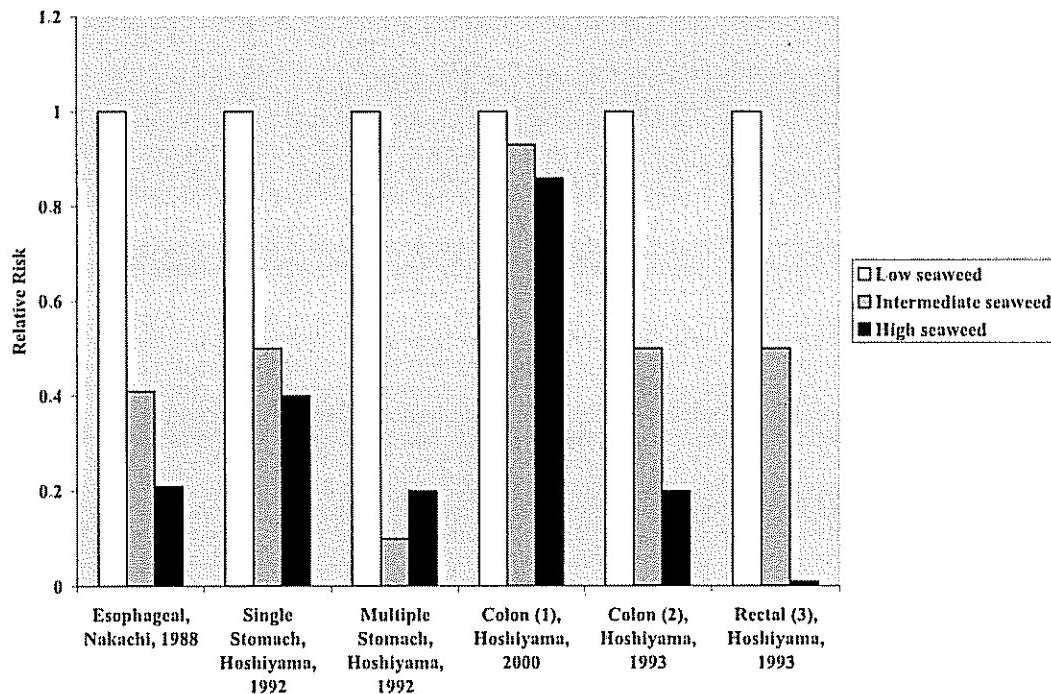
There is also one report in the medical literature of easy bruising that the authors' thought might have been related to taking seaweed supplements. None of the women in this study noticed bruising as a side effect from taking seaweed supplements.

Chronic benefits

13. The claims of SeaVegetation might be justified for some chronic conditions, based on folk medicine and traditional remedies that have been used for hundreds of years.

14. Archeological evidence of seaweed use dates back to the ancient sites of the Jomon period in Japan (13,000 to 300 B.C.) (Arasaki and Arasaki 1983). Written accounts of medicinal use of seaweed appeared in Ayurvedic (traditional medical tradition of India) from the 4th century BC (Misra and Sinha 1979); Traditional Chinese Medicine, in the Chinese "Materia Medica" of 2700 BC (Hoppe 1979); and in the "Ebers Papyrus," the Egyptian treatise on medical care, written approximately in 1550 BC (Loeser 1956). The medicinal uses of seaweed are vast and range from topical burn therapy to goiter therapy to softening of tumors (Schwimmer and Schwimmer 1955). The best supported claim is for its anticancer effects.

15. First, in reviewing the epidemiologic associations of seaweed consumption and cancer, all studies done in Japan with a habitual seaweed eating population, show a protective effect(Teas 2005). In the following figure, the relative impact of seaweed is presented.



1 Intermediate seaweed intake was defined as 2 – 4 times/week

2, 3 Intermediate seaweed intakes was defined as 5 - 7 times/week

In the affidavit by Christine Skibola, the abstract of the stomach cancer study by Hoshiyama was included. However the wording of the abstract is confusing, stating that, “dose-response relationships were observed for 3 dietary items (miso soup, fruits, and seaweed) in the multiple logistic regression analysis.” In the article, the dose response relationship was inversely related so that people with a higher frequency of seaweed consumption had significantly lower relative risks of both single and multiple stomach cancers. For single stomach cancers, there was a dose relationship. These data are presented in the figure above.

16. One study of Japanese immigrants living in Hawaii found an increased risk of prostate cancer with increased seaweed intake (Severson, 1989). However the specific

kinds of seaweed consumed are much more common in Hawaii than in Japan, and include *Aspargopsis taxiformis*, a red seaweed shown to contain mutagenic compounds.

17. Many studies in cell culture and animal models of cancer prevention and treatment with seaweed and seaweed extracts also support the likelihood that seaweed could be associated with decreased cancer incidence. Oddly enough, iodine, the dose limiting component of seaweed, might also be related to the lower breast cancer incidence found in women in Japan. The work of Funahashi and colleagues report protection from dimethylbenzanthracene (DMBA)-induced mammary tumors when iodine was given to the rats in their diet. As a possible mechanism, they reported a high correlation between serum iodine and apoptosis of mammary cancer cells (Funahashi and others 2001; Funahashi and others 1996; Funahashi and others 1999). These results, along with those we (Teas and others 1984) and others (Maruyama and others 2003; Takahashi and others 2000; Yamamoto and others 1987) have reported for dietary seaweed as inhibitory of DMBA-induced mammary tumors are consistent with the idea that seaweed, possibly via iodine, could be involved in breast cancer prevention.

Arthritis

18. Two reports presented at the American College of Nutrition in October, 2002 presented data showing significant pain reduction in 14 people with rheumatoid arthritis who took BioAstin, a derivative of Spirulina(Smith 2002). Spirulina is a cyanobacteria that produces high levels of the carotenoid astaxanthin. However the studies have not yet been published in peer-reviewed medical journals.

Fibromyalgia

19. Two studies of Chlorella, a green alga, have reported improvements in symptoms of fibromyalgia ((Merchant and Andre 2001; Merchant and others 2000). Twenty patients consumed both 10 g of 'Sun Chlorella' tablets and 100 mL of Chlorella liquid extract for 2 months. Overall, the patients reported 22% average decrease in pain. The subjective reports of the 18 subjects varied; 7 felt the supplements had improved their symptoms, 6 felt no change, and 5 felt their symptoms had worsened. In a follow-up study by Merchant, 55 patients with fibromyalgia were given 10 g of chlorella (in tablets) and 100 mL of a liquid chlorella extract each day for 2 or 3 months. Pain and overall quality of life were improved with the supplements.

Diabetes

20. A study done in rabbits showed various seaweed extracts, at a dose of 5 mg/kg, resulted in 18% reduction in glycemia in non-diabetic rabbits, and a 50% reduction in glycemia in diabetic rabbits. Although the effect of seaweed fiber may slow the gastric emptying time and hence stabilize blood sugar, only one clinical trial has specifically investigated the antidiabetic effects of seaweed in humans(Dumelod and others 1999). Focusing on seaweed as a source of soluble fiber, in a randomized crossover design, 10 normal fasting adults were given either arroz caldo or arroz caldo with carrageenan. Blood glucose levels were significantly lower 15, 30, 45, 60, and 90 minutes after consuming the seaweed supplemented meal ($p < .001$ at 30 minutes; $p < \text{or} = 0.05$ at the other time points). Using another way of comparing the effects, the mean glucose area

under the curve was significantly lower ($P < \text{or } = 0.01$) after consumption of the seaweed-supplemented meal (69.22 ± 32.94) than control (147.29 ± 53.34).

21. Invoking a different mechanism for lowering hyperglycemia, Jin and colleagues (Jin and others 2004) reported that *Laminaria japonica* extract significantly reduced blood glucose and oxidative stress caused by diabetes in rats.

22. In another study of alginic acid derived from *Laminaria angustata* given to rats, the gel significantly bound cholesterol and glucose in the stomach, inhibiting its absorption from the small intestine (Kimura and others 1996). The authors suggested seaweed derived compounds could be helpful in diabetes and obesity, by virtue of its non-digestible gelling properties. These compounds are likely to be similar to those found in whole seaweeds.

Conclusions:

Algae may well reduce symptoms of diabetes, fibromyalgia, arthritis, and could possibly prevent cancers.

I hereby declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Signed: Jane Tiss Date: June 9, 2005

Arasaki S, Arasaki T. 1983. Vegetables from the Sea. Tokyo: Japan Publications Inc.

Braverman LE, Ingbar SH, Vagenakis AG, Adams L, Maloof F. 1971. Enhanced susceptibility to iodine myxedema in patients with Hashimoto's disease. Journal of Clinical Endocrinology and Metabolism 82:S15-521.

Dumelod BD, Ramirez RP, Tiangson CL, Barrios EB, Panlasigui LN. 1999. Carbohydrate availability of arroz caldo with lambda-carrageenan. Int J Food Sci Nutr. 50(4):283-9.

- Misra A, Sinha R. 1979. Algae as drug plants in India. In: Hoppe HA, Levring T, Tanaka Y, editors. *Marine Algae in Pharmaceutical Science*. Berlin: Walter de Gruyter. p 237-242.
- Schwimmer M, Schwimmer D. 1955. The Role of Algae and Plankton in Medicine. New York: Grune & Stratton.
- Smith M. 2002. Sea Algae May Ease Carpal Tunnel Pain. WebMDHealth.
- Takahashi N, Ojika M, Dogasaki C, Nishizawa M, Fukuoka H, Sahara H, Sato N, Mori M, Kikuchi K. 2000. Substance isolated from the kelp rhizoid identified as L-tryptophan shows high inhibition of breast cancer. *Gan To Kagaku Ryoho*. 27(2):251-5.
- Teas J. 2005. Dietary Brown Seaweeds and Human Health Effects. In: Critchley AT, Masao Ohno and Danilo Largo, editor. *Seaweed Resources*. Univ. Amsterdam: Expert Centre for Taxonomic Identification.
- Teas J, Harbison ML, Gelman RS. 1984. Dietary seaweed (*Laminaria*) and mammary carcinogenesis in rats. *Cancer Research* 44(7):2758-61.
- Wolff J, Chaikoff IL. 1948. The inhibitory action of iodide upon organic binding of iodine by the normal thyroid gland. *Journal of Biological Chemistry* 172:855-6.
- Yamamoto I, Maruyama H, Moriguchi M. 1987. The effect of dietary seaweeds on 7,12-dimethyl-benz[a]anthracene-induced mammary tumorigenesis in rats. *Cancer Letters* 35(2):109-18.